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L2: Entry 1 of 20

File: PGPB

May 1, 2003

PGPUB-DOCUMENT-NUMBER: 20030082664

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20030082664 A1

TITLE: System for the detection of urease and method for using same

PUBLICATION-DATE: May 1, 2003

## INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Marshall, Barry J.	Dalkeith		AU	
Mendis, Aruni H.W.	Connolly		AU	
Chairman, Simon	Beaconsfield		AU	

US-CL-CURRENT: 435/18

## ABSTRACT:

A system and method for detecting bacterial infections in the gastrointestinal tract is disclosed. In one embodiment, the system includes a first composition separated from a second composition. The first composition contains urea in powdered form. The second composition, on the other hand, contains an indicator. A biopsy of a gastric sample is first contacted with the first composition and then placed in the second composition. The second composition indicates the presence of an enzyme that, in turn, indicates the presence of bacteria. In an alternative embodiment of the present invention, a biopsy of a gastric sample is contacted with a single composition. The composition contains urea in a powdered form combined with a dry indicator. Besides urea and a dry indicator, the composition can also contain an anti-caking agent.

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	Claims	KNOC
Draw Desc											

☐ 2. Document ID: US 20030082661 A1

L2: Entry 2 of 20

File: PGPB

May 1, 2003

PGPUB-DOCUMENT-NUMBER: 20030082661

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20030082661 A1

TITLE: Diagnostic testing system and method for detecting helicobacter pylori

PUBLICATION-DATE: May 1, 2003

## INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
McMichael, Donald J.	South Jordan	UT	US	
Peterson, Kristy	Salt Lake City	UT	US	
Marshall, Barry J.	Dalkeith		AU	
Mendis, Aruni H. W.	Connolly		AU	
Chairman, Simon	Beaconsfield		AU	

US-CL-CURRENT: 435/12

## ABSTRACT:

A system and method for detecting bacterial infections in the gastrointestinal tract is disclosed. The system includes a carrier having a first well and a second well. A first composition is disposed in the first well and contains urea in powdered form. A second composition is disposed in a second well and contains an indicator. A biopsy of a gastric sample is manipulated with a specimen-handling tool and is first contacted with the first composition and then placed in the second composition. The second composition indicates the presence of an enzyme, which, in turn, indicates the presence of bacteria.

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	Claims	KWIC
Draw Desc											

☐ 3. Document ID: US 20030077684 A1

L2: Entry 3 of 20

File: PGPB

Apr 24, 2003

PGPUB-DOCUMENT-NUMBER: 20030077684

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20030077684 A1

TITLE: Composition for the detection of gastrointestinal disorders

PUBLICATION-DATE: April 24, 2003

## INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Marshall, Barry J.	Dalkeith		AU	
Mendis, Aruni H.W.	Connolly		AU	
Chairman, Simon	Beaconsfield		AU	

US-CL-CURRENT: 435/18

## ABSTRACT:

A system and method for detecting bacterial infections in the gastrointestinal tract is disclosed. In one embodiment, the system includes a first composition separated from a second composition. The first composition contains urea in powdered form. The second composition, on the other hand, contains an indicator. A biopsy of a gastric sample is first contacted with the first composition and then placed in the second composition. The second composition indicates the presence of an enzyme that, in turn, indicates the presence of bacteria. In an alternative embodiment of the present invention, a biopsy of a gastric sample is contacted with a single composition. The composition contains urea in a powdered form combined with a dry indicator. Besides urea and a dry indicator, the composition can also contain an anti-caking agent.

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	Claims	KWIC
Draw Desc											

☐ 4. Document ID: US 20030077680 A1

L2: Entry 4 of 20

File: PGPB

Apr 24, 2003

PGPUB-DOCUMENT-NUMBER: 20030077680

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20030077680 A1

TITLE: Method for the detection of urease and method for using same

PUBLICATION-DATE: April 24, 2003

## INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Marshall, Barry J.	Dalkeith		AU	
Mendis, Aruni H.W.	Connolly		AU	
Chairman, Simon	Beaconsfield		AU	

US-CL-CURRENT: 435/12

## ABSTRACT:

A system and method for detecting bacterial infections in the gastrointestinal tract is disclosed. In one embodiment, the system includes a first composition separated from a second composition. The first composition contains urea in powdered form. The second composition, on the other hand, contains an indicator. A biopsy of a gastric sample is first contacted with the first composition and then placed in the second composition. The second composition indicates the presence of an enzyme that, in turn, indicates the presence of bacteria. In an alternative embodiment of the present invention, a biopsy of a gastric sample is contacted with a single composition. The composition contains urea in a powdered form combined with a dry indicator. Besides urea and a dry indicator, the composition can also contain an anti-caking agent.

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KWIC
Draw Desc	Image									

☐ 5. Document ID: US 20030007980 A1

L2: Entry 5 of 20

File: PGPB

Jan 9, 2003

PGPUB-DOCUMENT-NUMBER: 20030007980

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20030007980 A1

TITLE: Urease-based vaccine and treatment for helicobacter infection

PUBLICATION-DATE: January 9, 2003

## INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Michetti, Pierre	Lausanne		CH	
Corthesy-Theulaz, Irene	Lausanne		CH	
Blum, Andre	Romammotier		CH	
Davin, Catherine	Rule de Moulins		FR	
Haas, Rainer	Tubingen		DE	
Kraehenbuhl, Jean-Pierre	Rivaz		CH	
Saraga, Emilia	Lausanne		CH	

US-CL-CURRENT: 424/190.1; 424/234.1

## ABSTRACT:

Method of eliciting in a mammalian host a protective immune response to Helicobacter infection and treatment of Helicobacter infection by administering to the host an immunogenically effective amount of a Helicobacter urease or urease subunits as antigen. Vaccine compositions are also provided.

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	RMIC
Draw Desc	Image									

☐ 6. Document ID: US 20010012623 A1

L2: Entry 6 of 20

File: PGPB

Aug 9, 2001

PGPUB-DOCUMENT-NUMBER: 20010012623

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20010012623 A1

TITLE: Detection of H. pylori in the stomach

PUBLICATION-DATE: August 9, 2001

## INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Marshall, Barry	Dalkeith		AU	

US-CL-CURRENT: 435/34

## ABSTRACT:

A method for the in vivo detection of urease-producing helicobacter in the upper stomach is disclosed. The dense carrier is divided into two separate groups which are combined with separate reagent indicators, one of which also contains urea. The carriers are food soluble products, preferably sugar beads having a diameter of approximately 0.2 to 3.0 mm. The treated carriers and urea are encapsulated in a soluble capsule which is administered to a patient. The density of the carriers cause the capsule to migrate to the gastric mucosa, where the capsule, but not the reagents, is dissolved, placing the reagents and urea in direct contact with the gastric mucosa. The urea reacts with any urease present in the stomach by creating ammonia, which increases the pH in the immediate vicinity of the urea containing carrier and indicator beads. The two reagents react differently, through color change, to the increase in pH, which is viewed through use of an endoscope. A preferred first reagent is bromothymol blue (dibromothymolsulfonphthalein), which changes yellow in the presence of urease, and a preferred second reagent is phenol red (phenolsulfonphthalein), which turns red in the presence of urease.

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments
Draw Desc	Image								

KUMC

☐ 7. Document ID: US 6479278 B2

L2: Entry 7 of 20

File: USPT

Nov 12, 2002

US-PAT-NO: 6479278

DOCUMENT-IDENTIFIER: US 6479278 B2

TITLE: Detection of Helicobacter pylori in the stomach

DATE-ISSUED: November 12, 2002

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Marshall; Barry	Dalkeith 6009			AU

US-CL-CURRENT: 435/287.9; 435/34

## ABSTRACT:

A method for the in vivo detection of urease-producing helicobacter in the upper stomach is disclosed. The dense carrier is divided into two separate groups which are combined with separate reagent indicators, one of which also contains urea. The carriers are food soluble products, preferably sugar beads having a diameter of approximately 0.2 to 3.0 mm. The treated carriers and urea are encapsulated in a soluble capsule which is administered to a patient. The density of the carriers cause the capsule to migrate to the gastric mucosa, where the capsule, but not the reagents, is dissolved, placing the reagents and urea in direct contact with the gastric mucosa. The urea reacts with any urease present in the stomach by creating ammonia, which increases the pH in the immediate vicinity of the urea containing carrier and indicator beads. The two reagents react differently, through color change, to the increase in pH, which is viewed through use of an endoscope. A preferred first reagent is bromothymol blue (dibromothymolsulfonphthalein), which changes yellow in the presence of urease, and a preferred second reagent is phenol red (phenolsulfonphthalein), which turns red in the presence of urease.

7 Claims, 1 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 1

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments
Draw Desc	Image								

KUMC

☐ 8. Document ID: US 6290962 B1

L2: Entry 8 of 20

File: USPT

Sep 18, 2001

US-PAT-NO: 6290962

DOCUMENT-IDENTIFIER: US 6290962 B1

**\*\* See image for Certificate of Correction \*\***TITLE: Urease-based vaccine and treatment for helicobacter infection

DATE-ISSUED: September 18, 2001

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Michetti; Pierre	Lausanne			CH
Corthesy-Theulaz; Irene	Lausanne			CH
Blum; Andre	Romammotier			CH
Davin; Catherine	Nyon			CH
Haas; Rainier	Tubingen			CH
Kraehenbuhl; Jean-Pierre	Rivat			CH
Saraga; Emilia	Lausanne			CH

US-CL-CURRENT: 424/185.1; 424/184.1, 424/192.1, 424/193.1, 424/197.11, 424/203.1,  
424/234.1, 424/261.1, 424/278.1, 424/280.1, 424/282.1, 424/94.6, 514/234.5, 514/41

## ABSTRACT:

Method of eliciting in a mammalian host a protective immune response to Helicobacter infection and treatment of Helicobacter infection by administering to the host an immunogenically effective amount of a Helicobacter urease or urease subunits as antigen. Vaccine compositions are also provided.

72 Claims, 10 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 6

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KOMIC
Draw Desc	Image									

☐ 9. Document ID: US 6228605 B1

L2: Entry 9 of 20

File: USPT

May 8, 2001

US-PAT-NO: 6228605

DOCUMENT-IDENTIFIER: US 6228605 B1

TITLE: Detection of helicobacter pylori in the stomach

DATE-ISSUED: May 8, 2001

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Marshall; Barry J.	Earlsville	VA	22936	

US-CL-CURRENT: 435/34; 435/12

## ABSTRACT:

A method for the in vivo detection of urease-producing Helicobacter in the upper stomach is disclosed. The dense carrier is divided into two separate groups which are combined with separate reagent indicators, one of which also contains urea. The carriers are food soluble products, preferably sugar beads having a diameter of approximately 0.2 to 3.0 mm. The treated carriers and urea are encapsulated in a soluble capsule which is administered to a patient. The density of the carriers cause the capsule to migrate to the gastric mucosa, where the capsule, but not the reagents, is dissolved, placing the reagents and urea in direct contact with the gastric mucosa. The urea reacts with any urease present in the stomach by creating

ammonia, which increases the pH in the immediate vicinity of the urea containing carrier and indicator beads. The two reagents react differently, through color change, to the increase in pH, which is viewed through use of an endoscope. A preferred first reagent is bromothymol blue (dibromothymolsulfonphthalein), which changes yellow in the presence of urease, and a preferred second reagent is phenol red (phenolsulfonphthalein), which turns red in the presence of urease.

15 Claims, 1 Drawing figures  
Exemplary Claim Number: 1  
Number of Drawing Sheets: 1

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KWMC
Draw Desc	Image									

☐ 10. Document ID: US 6187556 B1

L2: Entry 10 of 20

File: USPT

Feb 13, 2001

US-PAT-NO: 6187556  
DOCUMENT-IDENTIFIER: US 6187556 B1

TITLE: Composition, kit, and method for detecting Helicobacter pylori in biopsy

DATE-ISSUED: February 13, 2001

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Lee; Jong-Hwa	Cheonan-city, Choongcheongnam-do			KR
Lee; Hak-Sung	Hanam-city Kyungki-do			KR
Roe; Im-Hwan	Seongnam-city, Kyungki-do			KR
Kim; Jung-Taik	Seongnam-city, Kyungki-do			KR
Hah; Yung-Chil	Seoul			KR
Choe; Tae-Boo	Seoul			KR

US-CL-CURRENT: 435/34; 435/12, 435/975

ABSTRACT:

Disclosed are a composition for detecting Helicobacter pylori including urea 0.5 to 4 percent by volume, potassium phosphate 0.05 to 0.2 percent by volume, phenate reagent solution 0.8 to 1.7 percent by volume, an indicator having a pK.sub.a of 6.5 to 8.5, 0.002 to 0.005 percent by volume, and a balance of water, a kit for detecting Helicobacter pylori using the composition and detecting method using the composition can determine quickly and accurately whether or not an infection by Helicobacter pylori exists, can obtain the same determination results after an elapse of time and can be used easily in an endoscope chamber.

8 Claims, 3 Drawing figures  
Exemplary Claim Number: 1  
Number of Drawing Sheets: 2

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KWMC
Draw Desc	Image									

☐ 11. Document ID: US 6156525 A

L2: Entry 11 of 20

File: USPT

Dec 5, 2000

US-PAT-NO: 6156525

DOCUMENT-IDENTIFIER: US 6156525 A

TITLE: Method for judging eradication of H. pylori based on rates of changes in the pepsinogen I/II ratio

DATE-ISSUED: December 5, 2000

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Furuta; Takahisa	Hamamatsu-shi, Shizuoka	433		JP

US-CL-CURRENT: 435/7.4; 435/7.1

## ABSTRACT:

A method of judging the eradication of H. pylori to judge whether the sample is positive or negative through a quick and easily operation is provided. A PG I value and a PG II value in the body fluids (e.g., in the blood) of an H. pylori positive patient are measured before the H. pylori eradicating treatment and after the passage of a period in which a substantially significant result occurs from the eradicating treatment, a PG I/PG II ratio in the body fluids (e.g., in the blood) is found, a rate of change in the PG I/PG II ratio in the body fluids (e.g., in the blood) is found before the H. pylori eradicating treatment and after the passage of the period in which a substantially significant result occurs from the eradicating treatment, and the change in the PG I/PG II ratio is used as a marker to indicate that H. pylori is eradicated.

9 Claims, 7 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 7

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments
Draw Desc	Image								

K00C

☐ 12. Document ID: US 5989840 A

L2: Entry 12 of 20

File: USPT

Nov 23, 1999

US-PAT-NO: 5989840

DOCUMENT-IDENTIFIER: US 5989840 A

TITLE: Estimation of active infection by heliobacter pylori

DATE-ISSUED: November 23, 1999

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
D'Angelo; Joseph P.	Miami	FL		
Zhe; Jin	Miami	FL		

US-CL-CURRENT: 435/7.32; 422/101, 422/50, 422/56, 435/12, 435/6, 436/113, 436/518



## ABSTRACT:

Disclosed is a diagnostic apparatus for estimating an active *Helicobacter pylori* infectious agent in saliva, comprising in combination an immunoassay chamber in which a first portion of said saliva is subjected to serological test for antibody to said infectious agent and a chemical reaction chamber in which a second portion of said saliva is subjected to chemical analysis for an ammonia constituent thereof.

17 Claims, 9 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 3

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KOMIC
Draw Desc	Image									

☐ 13. Document ID: US 5972336 A

L2: Entry 13 of 20

File: USPT

Oct 26, 1999

US-PAT-NO: 5972336

DOCUMENT-IDENTIFIER: US 5972336 A

TITLE: Urease-based vaccine against helicobacter infection

DATE-ISSUED: October 26, 1999

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Michetti; Pierre	Lausanne			CH
Blum; Andre	Lausanne			CH
Davin; Catherine	Lausanne			CH
Haas; Rainer	Tubingen			DE
Corthesy-Theulaz; Irene	Lausanne			CH
Kraehenbuhl; Jean-Pierre	Lausanne			CH
Saraga; Emilia	Lausanne			CH

US-CL-CURRENT: 424/184.1; 424/203.1, 424/234.1, 424/282.1, 424/450, 424/94.6,  
435/7.1, 435/7.32, 435/7.9, 514/234.5, 514/41, 530/323

## ABSTRACT:

Method of eliciting in a mammalian host a protective immune response to *Helicobacter* infection by administering to the host an immunogenically effective amount of a *Helicobacter urease* or *urease* subunits as antigen. Vaccine compositions are also provided.

26 Claims, 6 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 4

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KOMIC
Draw Desc	Image									

☐ 14. Document ID: US 5919463 A

L2: Entry 14 of 20

File: USPT

Jul 6, 1999

US-PAT-NO: 5919463

DOCUMENT-IDENTIFIER: US 5919463 A

TITLE: Clostridium difficle toxins as mucosal adjuvants

DATE-ISSUED: July 6, 1999

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Thomas, Jr.; William D.	Winchester	MA		
Monath; Thomas P.	Harvard	MA		
Zhang; Zhenxi	Cambridge	MA		
Torres-Lopez; Francisco Javier	San Clemente			MX
Lei; Wende	Cambridge	MA		
Lyerly; David M.	Radford	VA		
Moncrief; James S.	Christiansburg	VA		

US-CL-CURRENT: 424/239.1; 424/184.1, 424/192.1, 424/234.1, 424/236.1, 424/247.1,  
424/278.1, 424/94.6, 514/2, 530/300, 530/350, 530/825

## ABSTRACT:

The invention features methods and compositions for inducing protective and/or therapeutic immune responses to an antigen in a mammal. In these methods, an antigen is administered to the mammal with a toxin of a Clostridium (e.g., C. difficile), or a fragment or derivative thereof having adjuvant activity.

21 Claims, 18 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 9

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments
Draw Desc	Image								

K00C

☐ 15. Document ID: US 5507289 A

L2: Entry 15 of 20

File: USPT

Apr 16, 1996

US-PAT-NO: 5507289

DOCUMENT-IDENTIFIER: US 5507289 A

TITLE: System and method to diagnose bacterial growth

DATE-ISSUED: April 16, 1996

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Essen-Moller; Anders	Stockholm			SE

US-CL-CURRENT: 600/348; 600/301

## ABSTRACT:

A system and a method for monitoring intragastrintestinal concentrations of ammonium, and urease, during short or prolonged periods is presented, as an indicator of the presence and activity of an intragastrintestinal Helicobacter Pylori ("HP") infection, and of other bacterial infections that are similarly located. Ambulatory monitoring is possible. This system and method may be used in the evaluation of treatments for HP and other bacterial infection in the patient. A method is also presented to increase the diagnostic accuracy of the system and method by ingesting urea immediately before or during the monitoring.

30 Claims, 3 Drawing figures  
Exemplary Claim Number: 1  
Number of Drawing Sheets: 3

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KWMC
Draw Desc	Image									

☐ 16. Document ID: US 5498528 A

L2: Entry 16 of 20

File: USPT

Mar 12, 1996

US-PAT-NO: 5498528  
DOCUMENT-IDENTIFIER: US 5498528 A

TITLE: Detection of helicobacter pylori

DATE-ISSUED: March 12, 1996

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
King; Wing	San Francisco	CA	94121	

US-CL-CURRENT: 435/34; 435/29, 435/4, 435/810, 436/63, 436/74

ABSTRACT:

A method for detecting Helicobacter pylori is disclosed which method involves contacting a sample suspected of containing Helicobacter pylori with a medium which provides for substantially selective growth of Helicobacter pylori, incubating the sample with the medium for a time sufficient for detection of Helicobacter pylori growth and detecting the growth and thereby reducing the presence of Helicobacter pylori within the sample. The methodology employs a wide range of a different culture mediums which are modified specifically for the selective growth and specific detection of Helicobacter pylori. A typical medium includes Columbia broth supplemented with urea and a pH indicator. The methodology provides for a relatively high degree of sensitivity (i.e., small numbers of bacteria present within a sample are detected) as well high selectivity (i.e., the method provides for a low percentage of false positives). Various kits used in connection with the method are designed so that they can be used by unskilled users in an "at home" setting. The kits and methodology are economical, easily used and provide highly accurate results within a relatively short period of time (e.g., 3 days or less).

14 Claims, 0 Drawing figures  
Exemplary Claim Number: 1

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KWMC
Draw Desc	Image									

☐ 17. Document ID: US 5439801 A

L2: Entry 17 of 20

File: USPT

Aug 8, 1995

US-PAT-NO: 5439801

DOCUMENT-IDENTIFIER: US 5439801 A

TITLE: Test composition for the rapid detection of helicobacter pylori in gastric biopsy tissue

DATE-ISSUED: August 8, 1995

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Jackson; Frank W.	Mechanicsburg	PA		

US-CL-CURRENT: 435/12; 435/10, 435/34, 435/4, 435/40.5, 436/63, 436/811

## ABSTRACT:

An improved test composition for the diagnosis of gastric disease by detecting the presence of urease associated with H. pylori in a biopsy specimen is described in which the hydrolysis of urea by urease is detected by a combination of at least two dye indicators showing a color change and a positive result at an acid pH, in which the positive color is distinctive from the color of the biopsy specimen, and in which most positive results occur in 2-10 minutes and all occur in no more than 4 hours. Specific compositions are disclosed.

10 Claims, 0 Drawing figures

Exemplary Claim Number: 1

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments
Draw Desc	Image								

KMC

☐ 18. Document ID: US 5420016 A

L2: Entry 18 of 20

File: USPT

May 30, 1995

US-PAT-NO: 5420016

DOCUMENT-IDENTIFIER: US 5420016 A

TITLE: Test device and kit for detecting helicobacter pylori

DATE-ISSUED: May 30, 1995

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Boguslaski; Robert C.	Elkhart	IN		
Carrico; Robert J.	Elkhart	IN		

US-CL-CURRENT: 435/12; 106/2

## ABSTRACT:

A rapid method and easy to use unitized test device is disclosed for determining the

- presence of Helicobacter pylori in a biological tissue specimen by detecting the presence of urease in the tissue. The system basically utilizes a multilayer test device for separating and optimizing the various reactions involved, i.e. the urease in the specimen with a substrate and the ammonia generated thereby with an indicator element.

15 Claims, 5 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 1

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments
Draw. Desc	Image								

KOMIC

☐ 19. Document ID: US 5314804 A

L2: Entry 19 of 20

File: USPT

May 24, 1994

US-PAT-NO: 5314804

DOCUMENT-IDENTIFIER: US 5314804 A

TITLE: Test for Helicobacter pylori

DATE-ISSUED: May 24, 1994

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Boguslaski; Robert C.	Elkhart	IN		
Carrico; Robert J.	Elkhart	IN		

US-CL-CURRENT: 435/12; 435/10, 435/25, 435/34, 435/810, 436/811

ABSTRACT:

A rapid method and easy to use unitized test device is disclosed for determining the presence of Helicobacter pylori in a biological tissue specimen by detecting the presence of urease in the tissue. The system basically utilizes a multilayer test device for separating and optimizing the various reactions involved, i.e. the urease in the specimen with a substrate and the ammonia generated thereby with an indicator element.

9 Claims, 4 Drawing figures

Exemplary Claim Number: 1

Number of Drawing Sheets: 1

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments
Draw. Desc	Image								

KOMIC

☐ 20. Document ID: US 5439801 A MX 196023 B WO 9521937 A1 CA 2160916 C MX 9504461 A1

L2: Entry 20 of 20

File: DWPI

Aug 8, 1995

DERWENT-ACC-NO: 1995-283092

DERWENT-WEEK: 200124

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TITLE: Test compsns. for detection of Helicobacter pylori urease - contg. urea and a combination of pH indicator dyes

INVENTOR: JACKSON, F W

PRIORITY-DATA: 1994US-0195954 (February 14, 1994)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
US 5439801 A	August 8, 1995		007	C12Q001/58
MX 196023 B	April 14, 2000		000	G01N033/048
WO 9521937 A1	August 17, 1995	E	027	C12Q001/58
CA 2160916 C	March 30, 1999		000	C12Q001/58
MX 9504461 A1	May 1, 1999		000	C12Q001/58

INT-CL (IPC): A01 N 1/02; C12 Q 1/00; C12 Q 1/04; C12 Q 1/58; C12 Q 1/62; G01 N 33/048; G01 N 33/48

ABSTRACTED-PUB-NO: US 5439801A

BASIC-ABSTRACT:

Test compsns. for diagnosis of gastric disease by detection of urease associated with Helicobacter pylori in a biopsy specimen contain urea and at least 2 pH indicator dyes such that the colour change indicating the presence of H. pylori initially occurs at an acid pH and the resulting colour is distinct from the colour of the biopsy specimen. Also claimed is a compsn. as above contg. 0.5-2 wt.% urea, 0.4-1.4 wt.% agar, 0.2-1.2 wt.% N-octyl glucose and 1.5-3.5 mM NaH<sub>2</sub>PO<sub>4</sub>, the balance comprising a preservative, the indicator dyes and water, where the compsn. is in the form of a gel soft enough to envelop a biopsy specimen pushed into it and has an initial acid pH.

USE - The compsns. are esp. useful for diagnosis of peptic ulcers.

ADVANTAGE - Compared with prods. based on phenol red, e.g. 'Clotest' (RTM), the compsns. give a more distinctive colour change at a lower pH, which excludes false positive due to other bacteria, e.g. Proteus and Pseudomonas spp..

Full	Title	Citation	Front	Review	Classification	Date	Reference	Sequences	Attachments	KMNC
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Term	Documents
PHENOL	255630
PHENOLS	72233
RED	360605
REDS	1897
(1 AND (PHENOL ADJ RED)).USPT,PGPB,JPAB,EPAB,DWPI,TDBD.	20
(L1 AND PHENOL RED).USPT,PGPB,JPAB,EPAB,DWPI,TDBD.	20